PROACTIV PLUS PORE TARGETING TREATMENT- benzoyl peroxide gel Guthy-Renker LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Proactiv+ Pore Targeting Treatment

Drug Facts

Active ingredient

Benzoyl peroxide 2.5%

Purpose

Acne treatment gel

Use

for the management of acne.

Warnings

For external use only

When using this product

- do not use this product more than three times per day.
- skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- avoid unnecessary sun exposure and use a sunscreen.
- avoid contact with the eyes, lips, and mouth.
- avoid contact with hair and dyed fabrics, which may be bleached by this product.
- skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration.

Do not use if you

- have very sensitive skin
- are sensitive to benzoyl peroxide

Stop use and ask a doctor

• if irritation becomes severe.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- *Sensitivity Test for a New User:* Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated below.
- cleanse the skin thoroughly before applying this product.
- cover the entire affected area with a thin layer one to three times daily.

- because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor.
- if bothersome dryness or peeling occurs, reduce application to once a day or every other day.
- if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor.

Inactive ingredients

water, ethoxydiglycol, glycerin, prunus amygdalus dulcis (sweet almond) oil, polysorbate 80, polysorbate 60, sorbitan stearate, carbomer, potassium hydroxide, disodium EDTA, fragrance

Questions or comments?

Within US **1-800-950-4695**

Dist. by: Guthy-Renker® LLC • PO Box 14383 Palm Desert, CA 92255-4383

PRINCIPAL DISPLAY PANEL - 89 mL Bottle Box

Rodan & Fields **proactiv**⁺

Pore Targeting Treatment

3 FL. OZ. 89 mL

benzoyl peroxide acne treatment



PROACTIV PLUS PORE TARGETING TREATMENT

benzoyl peroxide gel

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11410-009
Route of Administration	TOPICAL	DEA Schedule	

ı	Active Ingredient/Active Moiety		
ı	Ingredient Name	Basis of Strength	Strength
	BENZOYL PEROXIDE (UNII: W9 WZN9 A0 GM) (BENZOYL PEROXIDE - UNII: W9 WZN9 A0 GM)	BENZOYL PEROXIDE	2.5 mg in 100 mL

Inactive Ingredients		
Ingredient Name	Strength	
WATER (UNII: 059QF0KO0R)		
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A118 X02B)		
GLYCERIN (UNII: PDC6A3C0OX)		
ALMOND OIL (UNII: 66 YXD4DKO9)		
POLYSORBATE 80 (UNII: 6OZP39ZG8H)		
POLYSORBATE 60 (UNII: CAL22UVI4M)		
SORBITAN MONOSTEARATE (UNII: NVZ4I0 H58 X)		
CARBOMER HOMOPOLYMER TYPE C (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 4Q93RCW27E)		
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)		
EDETATE DISO DIUM (UNII: 7FLD91C86K)		

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:11410-009-	1 in 1 BOX			
1	89 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product			
2 NDC:11410-009-	1 in 1 BOX			
2	30 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product			
3 NDC:11410-009- 23	1 in 1 BOX			
3	60 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product			

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC MONOGRAPH FINAL	part333D	0 1/0 3/20 13		

Labeler - Guthy-Renker LLC (608315453)

Revised: 2/2016 Guthy-Renker LLC